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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,129	10/09/2003	Greg Tong	TONGG-001A	1353

7663 7590 08/13/2007

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EXAMINER	
RANGREJ, SHEETAL	
ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
08/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/682,129	TONG, GREG	
	Examiner	Art Unit	
	Sheetal R. Rangrej	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Prosecution History Summary

1. Claims 1-28 are pending.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "20" and "36" have both been used to designate "unit dose card"; because they include the following reference character(s) not mentioned in the description: 170 (figure 7). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: paragraph 0046 lists a path name to a document that can not be referenced (page 20).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudy et al. (U.S. Publication No. 2004/0088187) in view of Kerfoot, Jr. (U.S. Patent No. 5,390,796) and further in view of Reference U.

6. As per claim 1, Chudy teaches a method of redistributing a medication, the method comprising the steps of receiving a request to fill a prescription **(Chudy: para. 0079)** and distributing the assembled unit doses to the patient care facility **(Chudy: para. 0123)**.

Chudy does not teach assembling the unit doses of medication based upon the prescription with each of the unit doses being individually identified with a lot number and an expiration date. Chudy also does not teach receiving an unused portion of the unit doses from a patient care facility, storing the unused unit doses and redistributing the unit doses within an indicated expiration date.

Kerfoot teaches a method of redistributing a medication, the method comprising the step of assembling the unit doses of medication based upon the prescription with each of the unit doses being individually identified with a lot number and an expiration date **(Kerfoot: col. 2, 30-37)**.

One of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teachings of Chudy and Kerfoot with the motivation that pharmacy personnel are required to make complex decisions and undertake tasks to fulfill the prescription orders such as making judgments about medications and products best suited to the customer's needs and the most efficient path by which to locate, obtain, package, and dispense the contents of each prescription order **(Chudy: para. 0006)**.

Kerfoot does not teach receiving an unused portion of the unit doses from a patient care facility, storing the unused unit doses, and redistributing the unit doses within an indicated expiration date.

Reference U discloses the position of The American Society of Consultant Pharmacists (ASCP) on the return and reuse of medications to the dispensing pharmacy (i.e. receiving an unused portion of the unit doses from a patient care facility) only if in the professional judgment of the pharmacist, the medications meet all federal and state standards (i.e. the drug is not expired) and follow policies and procedures for the appropriate storage (i.e. storing the unused unit doses) and handling of medications **(Reference U: p. 2, section: the ASCP position)**.

One of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teachings of Chudy in view of Kerfoot with Reference U with the motivation that good prescription drugs were being wasted creating an unnecessary costs being drained **(Reference U: p. 1, section: Medication waste in long-term care facilities)**.

7. As per claim 2, Chudy and Reference U do not teach wherein step assembling unit doses of medication comprises: 1) packaging each of the unit doses individually; and 2) indicating the lot numbers and the expiration dates on each of the respective packaged unit doses.

Kerfoot teaches wherein step assembling unit doses of medication comprises: 1) packaging each of the unit doses individually **(Kerfoot: figure 7, 43)**; and 2) indicating the lot numbers and the expiration dates on each of the respective packaged unit doses **(Kerfoot: col. 2, 30-37)**.

The motivation to combine the teachings is the same as claim 1.

8. As per claim 3, Chudy and Reference U do not teach wherein the indicated lot numbers and the expiration dates on each of the individually packaged unit doses are different from each other.

Kerfoot teaches wherein the indicated lot numbers and the expiration dates on each of the individually packaged unit doses are different from each other **(Kerfoot: col. 2, 30-37)**. The examiner interprets that since the unit doses are individually packaged, the expiration date and the lot numbers could be different since they are not coming from a bulk container.

The motivation to combine the teachings is the same as claim 1.

9. As per claim 4, Chudy and Reference U do not teach wherein distributing the assembled unit doses comprises: 1) obtaining a unit dose card with a medication receptacle; 2) inserting the unit doses into the medication receptacle of the unit dose card; and 3) enclosing the medication receptacle of the unit dose card.

Kerfoot teaches wherein distributing the assembled unit doses comprises: 1) obtaining a unit dose card with a medication receptacle **(Kerfoot: figure 5)**; 2) inserting the unit doses into the medication receptacle of the unit dose card **(Kerfoot: figure 7)**; and 3) enclosing the medication receptacle of the unit dose card **(Kerfoot: col. 4, 65 to col. 5, 5)**.

The motivation to combine the teachings is the same as claim 1.

10. As per claim 5, Chudy teaches wherein the medication receptacle is formed separately with the unit dose card **(Chudy: para. 0080-0081)**.

11. As per claim 6, Chudy and Reference U do not teach wherein the medication receptacle is a bag attached to the unit dose card.

Kerfoot teaches wherein the medication receptacle is a bag attached to the unit dose card **(Kerfoot: figure 7; col. 3, 21-31)**.

The motivation to combine the teachings is the same as claim 1.

12. As per claim 7, Chudy and Reference U do not teach wherein the medication receptacle is formed unitarily with the unit dose card.

Kerfoot teaches wherein the medication receptacle is formed unitarily with the unit dose card **(Kerfoot: figure 7)**.

The motivation to combine the teachings is the same as claim 1.

13. As per claim 8, Chudy and Reference U do not teach wherein the unit dose card is an envelope and the medication receptacle is a pouch of the envelope.

Kerfoot teaches wherein the unit dose card is an envelope and the medication receptacle is a pouch of the envelope **(Kerfoot: figure 7)**.

The motivation to combine the teachings is the same as claim 1.

14. As per claim 9, Chudy and Reference U do not teach wherein enclosing the medication receptacle comprises: i) indicating patient information on the unit dose card; and ii) indicating prescription information on the unit dose card.

Kerfoot teaches wherein enclosing the medication receptacle comprises: i) indicating patient information on the unit dose card **(Kerfoot: figure 5, 33; col. 2, 12-20)**; and ii) indicating prescription information on the unit dose card **(Kerfoot: figure 5, 32; col. 2, 12-20)**.

The motivation to combine the teachings is the same as claim 1.

15. As per claim 10, Chudy and Kerfoot do not teach wherein receiving the unused portion of the unit doses comprises: 1) identifying an amount of the unused portion of the unit doses; 2)

completing a unit dose card provided with the distributed unit doses to record the identified unused portion of the unit doses; and 3) crediting the patient care facility for the identified unused portion of the unit doses.

Reference U discloses that The American Society of Consultant Pharmacists (ASCP) supports the return and reuse of medications to the dispensing pharmacy only if a mechanism is in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source. The examiner interprets that in order to credit the payer source for the unused the drugs, it has to identify the amount of unit doses that are unused and record the amount of unused unit doses so it can proportionally reimburse or credit **(Reference U: p. 2)**.

The motivation to combine the teachings is the same as claim 1.

16. As per claim 11, Chudy teaches wherein storing the unit doses further comprises removing select ones of the unit doses from storage based upon the lot numbers **(Chudy: para. 0174)**.

17. As per claim 12, Chudy teaches wherein storing the unit doses further comprises removing select ones of the unit doses from storage based upon the expiration dates **(Chudy: para. 0174)**.

18. As per claim 13, Chudy teaches a method of mitigating a medication cost for a medication, the method comprising the steps of: receiving a request to fill a prescription for the medication of a patient serviced by a patient care facility **(Chudy: para. 0079)** and distributing the assembled unit doses to the patient care facility **(Chudy: para. 0123)**.

Chudy does not teach a method of mitigating a medication cost for a medication, the method comprising the steps of: -assembling unit doses of the medication based upon the

prescription, each of the unit doses being individually identified with a lot number and an expiration date; -receiving an unused portion of the unit doses from the patient care facility; -identifying an amount of the unused portion of the unit doses; and
-crediting the patient care facility for the identified unused portion of the unit doses to mitigate the medication cost of the medication.

Kerfoot teaches a method of mitigating a medication cost for a medication, the method comprising the steps of: -assembling unit doses of the medication based upon the prescription, each of the unit doses being individually identified with a lot number and an expiration date **(Kerfoot: col. 2, 30-37)**.

One of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teachings of Chudy and Kerfoot with the motivation that pharmacy personnel are required to make complex decisions and undertake tasks to fulfill the prescription orders such as making judgments about medications and products best suited to the customer's needs and the most efficient path by which to locate, obtain, package, and dispense the contents of each prescription order **(Chudy: para. 0006)**.

Kerfoot does not teach a method of mitigating a medication cost for a medication, the method comprising the steps of -receiving an unused portion of the unit doses from the patient care facility; -identifying an amount of the unused portion of the unit doses; and -crediting the patient care facility for the identified unused portion of the unit doses to mitigate the medication cost of the medication.

Reference U discloses that The American Society of Consultant Pharmacists (ASCP) supports the return and reuse of medications to the dispensing pharmacy only if a mechanism is

in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source. The examiner interprets that in order to credit the payer source for the unused the drugs, it has to identify the amount of unit doses that are unused and record the amount of unused unit doses so it can proportionally reimburse or credit **(Reference U: p. 2)**.

One of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teachings of Chudy in view of Kerfoot with Reference U with the motivation that good prescription drugs were being wasted creating an unnecessary costs being drained **(Reference U: p. 1, section: Medication waste in long-term care facilities)**.

19. For claims 14-21, please see citations and motivations of claims 2-9, respectively.

20. As per claim 22, Kerfoot does not teach storing the unused portion of the unit doses and storing them based on lot numbers.

Chudy teaches storing medications (i.e. unit doses) based on lot numbers **(Chudy: para. 0174)**, while Reference U teaches that proper storage and handling of the unused medications should be practiced **(Reference U: p. 2)**.

The motivation to combine the teachings is the same as claim 1.

21. As per claim 23, Kerfoot does not teach storing the unused portion of the unit doses and storing them based on expiration dates.

Chudy teaches storing medications (i.e. unit doses) based on expiration dates **(Chudy: para. 0174)**, while Reference U teaches that the returned medications should meet all federal and state standards, which includes within the expiration dates.

The motivation to combine the teachings is the same as claim 1.

22. As per claim 27, Chudy and Kerfoot do not teach crediting the patient care facility comprising reimbursing the patient care facility.

Reference U discloses that The American Society of Consultant Pharmacists (ASCP) supports the return and reuse of medications to the dispensing pharmacy only if a mechanism is in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source. The examiner interprets that in order to credit the payer source for the unused the drugs, it has to identify the amount of unit doses that are unused and record the amount of unused unit doses so it can proportionally reimburse or credit **(Reference U: p. 2)**. The examiner also interprets that crediting is a form of reimbursing.

The motivation to combine the teachings is the same as claim 1.

23. As per claim 28, Chudy and Kerfoot do not teach redistributing the unit doses within an indicated expiration date.

Reference U discloses the position of The American Society of Consultant Pharmacists (ASCP) on the return and reuse of medications to the dispensing pharmacy only if in the professional judgment of the pharmacist, the medications meet all federal and state standards (i.e. the drug is not expired) and follow policies and procedures for the appropriate storage and handling of medications **(Reference U: p. 2, section: the ASCP position)**.

The motivation to combine the teachings is the same as claim 1.

24. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudy et al. (U.S. Publication No. 2004/0088187) in view of Kerfoot, Jr. (U.S. Patent No. 5,390,796) and further in view of Reference U and Sisilli (U.S. Patent No. 5,779,543).

25. As per claim 24, Chudy and Kerfoot do not teach identifying an amount of the unused portion of the unit doses comprises: 1) separating a unit dose card with provider's and facility's card portions from the unit doses; and 2) recording the amount of the unused portion of the unit doses on the provider's and facility's card portions of the unit dose card.

Reference U discloses that The American Society of Consultant Pharmacists (ASCP) supports the return and reuse of medications to the dispensing pharmacy only if there is a system in place to track re-stocking and reuse to allow medications to be recalled if required, while Sisilli teaches a form with vertical lines of separation (i.e. perforation) such that there is a left-hand side and a right-hand side, resulting in two sets of documents intended for separate entities **(Sisilli: col. 2, 12-24)**. As one skilled in the art, it could be noted that the Sisilli's invention could be used with ASCP's system to help track the re-stocking and reuse of medications.

The motivation to combine the teachings of Chudy, Kerfoot, and Reference U is the same as claim 1.

One of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teachings of Chudy in view of Kerfoot with Reference U and Sisilli with the motivation that when a business transaction involves several documents having common subject matter, it would make it easier to simplify the preparation of such documents **(Sisilli: col. 1, 15-23)**.

26. As per claim 25, Chudy and Kerfoot do not teach recoding the amount of the unused protion comprises: i) separating the provider's and facility's card portions of the unit dose card; ii) retaining the provider's card portion of the unit dose card; and iii) sending the facility's card portion of the unit dose card to the patient care facility.

Reference U discloses that The American Society of Consultant Pharmacists (ASCP) supports the return and reuse of medications to the dispensing pharmacy only if there is a system in place to track re-stocking and reuse to allow medications to be recalled if required, while Sisilli teaches a form with vertical lines of separation (i.e. perforation) such that there is a left-hand side and a right-hand side, resulting in two sets of documents intended for separate entities **(Sisilli: col. 2, 12-24)**. The examiner interprets that since they are intended for separate entities, one could be retained by the provider and the other could be sent to the facility.

The motivation to combine the teachings of Chudy, Kerfoot, and Reference U is the same as claim 1.

The motivation to combine the teachings of Chudy, Kerfoot, Reference U, and Sisilli is the same as claim 24.

27. As per claim 26, Chudy, Kerfoot, and Reference U do not teach wherein the unit dose card is perforated between the provider's and facility's card portions.

Sisilli teaches wherein the unit dose card is perforated between the provider's and facility's card portions **(Sisilli: figure 3, 36)**.

The motivation to combine the teachings of Chudy, Kerfoot, Reference U, and Sisilli is the same as claim 24.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheetal R. Rangrej whose telephone number is 571-270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRR

SRR 8/2/07

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